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(71) Applicant: REGENERATION TECHNOLOGIES, INC. [US/US]; 1 Innovation Drive, Alachua, FL 32615 (US).

(72) Inventors: BIANCHI, John, R.; 4621 S.W. 85th Drive, Gainesville, FL 32608 (US). CARTER, Kevin, C.; 8502 N.W. 35th Road, Gainesville, FL 32606 (US). SANDER, Tom; 1 Innovation Drive, Alachua, FL 32615 (US). MILLS, C., Randal; 1 Innovation Drive, Alachua, FL 32615 (US). DONDA, Russell, S.; 1 Innovation Drive, Alachua, FL 32615 (US). SPENCER, Randal; 1 Innovation Drive, Alachua, FL 32615 (US). ESCH, Michael; 1 Innovation Drive, Alachua, FL 32615 (US). BERNHARDT, Andy; 1 Innovation Drive, Alachua, FL 32615 (US). LEE, Daniel, R.; 1 Innovation Drive, Alachua, FL 32615 (US). WEBECK, Ilsa; 1 Innovation Drive, Alachua, FL 32615 (US).

(74) Agent: VAN DYKE, Timothy, H.; Bencen & Van Dyke, P.A., 1630 Hillcrest Street, Orlando, FL 32803 (US).

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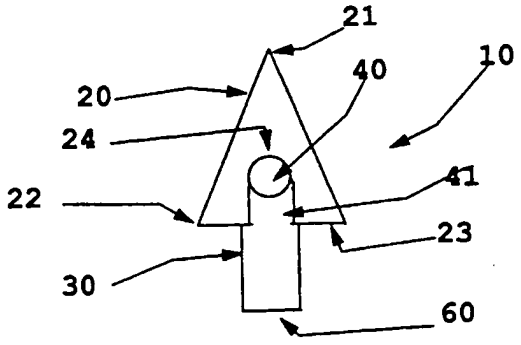
(54) Title: SUTURE SPEAR



(57) Abstract: A substantially cylindrical or wedge-shaped cortical bone implant wherein one end of the cylinder or wedge tapers to a sharp point and which comprises one or more through-channel(s) for receipt of suture(s), is disclosed for fixation of tissues to bone or other tissues of sufficient strength to provide solid fixation of tissue to which the implant is affixed. The implant optionally has a circumferential, longitudinal or angled barbs to enhance structural and retention characteristics of the implant. Certain embodiments of the invention include portions of the implant in a partially or fully demineralized state, such that added flexibility is imparted to the demineralized or partially demineralized segment. Additionally, embodiments of this invention optionally include threaded portions, fluted portions or slotted portions, depending on the desired implantation means and retention characteristics. The implant is optimally configured for a single step impaction implantation, although other forms of implantation are also contemplated.

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TITLE OF THE INVENTION
SUTURE SPEAR

REFERENCES TO RELATED APPLICATIONS

This application is a continuation-in-part to prior pending application Serial No. 09/360,584, filed on July 26, 1999.

FIELD OF THE INVENTION

This invention relates to a new implant made from bone for securing sutures and tissues to bone, to devices for implantation of the suture spear, and to methods of making and use thereof.

BACKGROUND OF THE INVENTION

In the field of orthopedics, a wide variety of devices have been developed to assist in the fixation of tissues to bone, frequently through provision of means for fixing sutures to bone. See, for example, U.S. Patent Nos. 4,409,974; 4,632,100; 4,712,550; 5,037,422; 5,141,520; 5,156,616; 5,372,604; 5,403,348; 5,496,348; 5,500,001; 5,522,846; 5,527,342; 5,527,343; 5,534,012; 5,549,630; 5,569,305; 5,571,139; 5,584,862; 5,645,589; 5,683,418; 5,690,649; 5,713,921; 5,715,942; 5,718,717; 5,720,765; 5,720,766; 5,725,557; 5,733,306; 5,743,914. In general, the fixation devices known in the art are metallic, plastic or resorbable synthetic devices which require additional insertion devices and frequently pre-drilling of cavities for receipt of the fixation devices. Fixation devices made from metal, due to the differences between bone and metal, may work themselves loose or create other problems which require surgical removal of the device. In addition, for devices known in the art where pre-drilling is required, the surgical time for installation is frequently unacceptably prolonged. Accordingly, there remain needs in the art for new fixation devices or implants which overcome limitations in the existing devices. The present invention provides a suture spear made from cortical bone which is inserted directly into bone, without the need for pre-

drilling, and because the suture spear itself is made from bone, the spear is incorporated into the recipient bone over time, eliminating the need for subsequent surgical removal of a foreign, metallic or plastic body.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A shows a side view of a first embodiment of the suture spear of this invention.

Figure 1B shows a side view of a first embodiment of the suture spear of this invention with a suture inserted through a suture canal formed in said suture spear.

Figure 2A shows a side view of a second embodiment of the suture spear of this invention.

Figure 2B shows a side view of a second embodiment of the suture spear of this invention with a suture inserted through a suture canal formed in said suture spear.

Figure 3A shows a side view of a third embodiment of the suture spear of this invention.

Figure 3B shows a side view of a third embodiment of the suture spear of this invention with a suture inserted through a suture canal formed in said suture spear.

Figure 4A shows a side view of a fourth embodiment of the suture spear of this invention.

Figure 4B shows a side view of a fourth embodiment of the suture spear of this invention with a suture inserted through a suture canal formed in said suture spear.

Figure 5A shows a side view of a fifth embodiment of the suture spear of this invention.

Figure 5B shows a side view of a fifth embodiment of the suture spear of this invention with a suture inserted through a suture canal formed in said suture spear.

Figure 6A shows a side view of a sixth embodiment of the suture spear of this invention.

Figure 6B shows a side view of a sixth embodiment of the suture spear of this invention with a suture inserted through a suture canal formed in said suture spear.

Figure 7A shows a side view of a seventh embodiment of the suture spear of this invention.

Figure 7B shows a side view of a seventh embodiment of the suture spear of this invention with a suture inserted through a suture canal formed in said suture spear.

Figure 8A shows a side view of an eighth embodiment of the suture spear of this invention.

Figure 8B shows a side view of an eighth embodiment of the suture spear of this invention with a suture inserted through a suture canal formed in said suture spear.

Figure 9A shows a side view of a first embodiment of an insertion device for implantation of the suture spear of this invention.

Figure 9B shows the insertion device with a suture spear loaded therein.

Figure 9C shows a side view of a further embodiment of the implant insertion device of this invention with an embodiment of the suture spear of this invention loaded therein.

Figure 10A shows a side view of a further embodiment of the suture spear of this invention comprising a flange for tacking tissue to bone.

Figure 10B shows a cross sectional view of the suture spear having a flange after having been impacted into recipient bone.

Figure 11A shows a schematic view of one embodiment of the suture spear of this invention.

Figure 11B shows a rear view of the suture spear, looking from the rear conical body toward the pointed head portion of the spear.

Figure 11C shows a side view of the suture spear of this invention showing a forward suture canal and specific dimensions for the spear.

Figure 11D shows a side view, rotated ninety degrees from the view shown in figure 11C, with additional specific dimensions of the suture spear.

Figure 12A shows a perspective view of a further embodiment of the suture spear of this invention having a rounded tip and an inscribed groove, rather than or in addition to a through canal.

Figure 12B shows a cross-sectional side view of the suture spear shown in figure 12A along line A-A in figure 12C.

Figure 12C shows an external side view with optional dimensions in millimeters for one embodiment of the suture spear shown in figure 12A.

Figure 12D shows an end-on frontal view of the rounded tip of the suture spear shown in figure 12A.

Figure 12E shows a cross-sectional view along line B-B shown in figure 12C viewed toward the rear.

Figure 12F shows an end-on rear view of the insertion hole and rear end of the suture spear shown in figure 12A.

Figure 13A shows an external side view of one embodiment of an insertion device for the suture spear shown in figure 12A.

Figure 13B shows a cross-sectional side view of the insertion device shown in figure 13A along section line A-A.

Figure 14 shows the suture spear of figure 12A mounted on the tip of the insertion device of figure 13A, with a suture mounted thereon and a retainer sleeve mounted on the shaft of the insertion device.

Figure 15 shows impact curves with and without spring damper in inserter.

SUMMARY OF THE INVENTION

A substantially cylindrical or wedge-shaped cortical bone implant wherein one end of the cylinder or wedge tapers to a sharp point and which comprises one or more through-channel(s) for receipt of suture(s), is disclosed for fixation of tissues to bone or other tissues of sufficient strength to provide solid fixation of tissue to which the implant is affixed. The implant optionally has a circumferential, longitudinal, spiral or angled barbs to enhance structural and retention characteristics of the implant. Certain embodiments of the invention include portions of the implant in a partially or fully demineralized state, such that added flexibility and fracture resistance is imparted to the demineralized or partially demineralized segment. Additionally, embodiments of this invention optionally include threaded portions, fluted portions or slotted portions, depending on the desired implantation means and retention characteristics. The implant is optimally configured for a single step impaction implantation, although other forms of implantation are also contemplated.

Accordingly, it is one object of this invention to provide an improved suture anchor made from cortical bone.

A further object of this invention is to provide a suture spear made from bone comprising a conical, trocar, wedge-shaped or other sharp point configuration which may be directly impacted into recipient bone.

A further object of this invention is to provide a suture anchor which may be inserted in a single step, without the need for a separate tapping or cortex puncture step.

A further object of this invention is to provide a suture anchor made from bone comprising a point having a thread, for turning the anchor into recipient bone.

Another object of this invention is to provide a suture spear comprising segments of bone that are partially or completely demineralized.

Another object of this invention is to provide a suture anchor which exhibits strong compressive properties of cortical bone.

Another object of this invention is to provide a suture spear which remodels into host bone for long-term fixation of sutures, which does not typically occur with synthetic or metallic implant suture anchors.

A further object of this invention is to provide a suture spear to which one or a plurality of suture lines may be attached.

A further object of this invention is to provide an improved method for attaching tissues, such as ligaments or tendons, or any other tissue, to bone.

Further objects and advantages of this invention will be appreciated from a review of the complete disclosure and claims appended hereto.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

It will be understood that the term "suture" as used herein refers to any commonly used thread, suture, or other type of string or tissue material that can be used to fix a suture spear or anchor to other tissue.

The term "skirt" and "barb" may be used synonymously, except that the term "skirt" is generally applied to a continuous circumferential feature, while the term "barb" is generally intended to mean a skirt that is in some way discontinuous. A substantially cylindrical or wedge-shaped cortical bone implant wherein one end of the cylinder or wedge tapers to a sharp point and which comprises one or more through-channel(s) for receipt of suture(s), is disclosed for fixation of tissues to bone or other tissues of sufficient strength to provide solid fixation of tissue to which the implant is affixed. The implant optionally has circumferential, longitudinal or angled barbs or skirts, to enhance structural and retention characteristics of the implant. Certain embodiments of the invention include portions of the implant in a partially or fully demineralized state, such that added flexibility is imparted to the demineralized or partially demineralized segment. Additionally, embodiments of this invention optionally include threaded portions, fluted portions or slotted portions, depending on the desired implantation means and retention characteristics. In some embodiments of the invention, the implant is shown with a suture receiving canal running transversely through the long axis of the implant, with the canal passing through a forward or rearward skirt, to form barbs on the cylindrical portion of the implant. It will be appreciated that the canal may be situated behind a skirt or barb, and that the forward point of the implant may be situated behind a cylindrical portion of the implant in the form of a skirt, rather than being a continuous, tapered point.

In one embodiment of this invention, because of the elastic properties of the bone from which the suture spear of this invention is formed, it is not necessary for any portion of the implant to be demineralized. The implant is fashioned from a selected piece of cortical bone and simply hammered into place, piercing the cortex of bone into which it is to be implanted, thereby fixing in place any tissue

attached to the suture spear. Alternatively, to add flexibility to the implant, or to alter the physical and biological properties of the implant, portions thereof may be slightly or fully demineralized. In one embodiment, a trailing extension is provided on the suture spear, which is demineralized to form a flexible "tail" to which tissue may be directly sutured, without the need to bury suture. The demineralized strip, flap or tail provides a flexible portion of the implant with increased area for reattaching tendons, ligaments or other tissue to bone. Furthermore, while in one embodiment of the invention, the head of the suture spear is unthreaded, various embodiments of the implant include a head which is slotted, fluted, or threaded, including a standard helical thread and variations thereof. In one specific embodiment, the head is threaded in such a way as to exhibit alternating first and second helical threads running substantially parallel with each other along the head of the suture spear. In a variant of this specific embodiment, the first and second threads exhibit diameters substantially different from each other, thereby exhibiting a high-low thread configuration. In yet a further embodiment, the suture spear may comprise a plurality of helical threads, each exhibiting different diameters. In yet a further embodiment, the implant exhibits parallel but out-of-phase threads. It will be appreciated that, while the following disclosure provides specific views in various figures showing one feature of the invention for purposes of simplicity and clarity, in fact combinations of the diagrammed features may be included in additional embodiments of the invention, without departing from the scope and intent of the present disclosure. Thus, while one figure shows a threaded head on an implant having only one retention means, and a second figure shows an implant having two sets of retention means, this disclosure should be interpreted to include an embodiment wherein a threaded head and two retention means are included in a single implant embodiment.

One unique aspect of the suture spear of the present invention is that it is made from bone of sufficient strength to permit a single-step impaction implant procedure to be achieved. In addition, host bone/tissue attaches to the implant of this invention, which remodels over time to recipient bone, thereby providing long-term suture attachment and thereby minimizing or eliminating the chance for

anchor loosening or pull-out, a problem that may occur with synthetic or metal suture anchors known in the art.

Referring now to the figures, there is provided in figure 1 a first embodiment **10** of the implant of this invention, showing a substantially conical head portion **20** and a substantially cylindrical body portion **30**, which is integrally connected with said conical head portion **20**. In this embodiment, the substantially conical head portion extends for a forward bone penetrating tip **21** to a wider diameter portion **22**, referred to herein as a skirt, which upon seating of the implant of this invention inside a recipient bone, provides a substantial resistive effect through retention by the inside surface of the recipient bone against the retention surface **23** of said head portion **20**. Through said conical head portion **20** and said substantially cylindrical body portion **30** is a transverse canal **40**, through which a suture **50** is loaded. Finally, the implant **10** has an impaction end portion **60** which is substantially flat, for loading into any appropriate loading means, (see figure 9 for one example of an implant driver which may be used according to this invention), or for direct impaction with a mallet. In order to protect the suture as the implant **10** is driven into bone via the head portion **20** and impaction at the impaction end portion **60**, the implant **10** is preferably provided with a channel **41** in which the suture **50** may lodged. Those skilled in the art will appreciate that the conical head **20** as represented in figure 1 may be designed to have different shapes than a cone. Thus, for example, a wedge-shaped head (which would appear similar from a side view to the appearance of the conical head shown in figure 1) could be used. Other variations and modifications of the head design portion **20** as may be suggested by the instant disclosure and which provide sufficient strength to permit the cortical bone implant to penetrate into an implant bone site upon impaction of the implant **10** against the surface of the recipient bone come within the scope of this invention and the claims appended hereto.

Upon impaction against a recipient bone, the bone implant shown in figure 1 has sufficient inherent flexibility that the skirt portion **22** penetrates into bone, without cracking, to permit efficient penetration of the suture spear **10** into the recipient bone. However, in order to enhance the survivability of the implant, in some

circumstances, it is desirable to demineralize or partially demineralize portions of the implant **10**. Prime among the portions of the implant to be demineralized or partially demineralized to enhance flexibility are the skirt portion, **22**, or just the peripheral edges thereof, and a portion of the head **24** referred to herein as the hinge. Demineralization or partial demineralization of bone is a procedure that is well known in the art. Accordingly, the implant **10** or specific portions thereof are exposed to acid leaching of minerals, using, for example, one normal hydrochloric acid or the like for sufficient time to leach out a sufficient percentage of minerals to increase the implant portion's elasticity. Care should be taken, however, not to demineralize the implant to such an extent that upon impaction into a recipient bone site, the suture spear is so flexible that it may become loosened from its site of implantation. Typically, leaching of between about one to twenty-five percent of the mineral from a particular site on the implant is sufficient to confer desired properties of elasticity such that fracture of the implant upon impaction is minimized, while at the same time retaining sufficient implant rigidity to ensure a secure impaction of the implant into host bone.

The implant shown in figure 1 is preferably machined from a dowel of cortical bone, either obtained as autograft, allograft or xenograft. The bone is desirably cleaned of extraneous debris, proteins and any potentially pathogenic organisms. This is achieved by treatment with ethanol, peroxide, sonication, vapor phase sterilants, irradiation and the like. It will be appreciated that it is preferred for the donor of the implant bone from which the implant of this invention is machined should be healthy and free of any known diseases. Where human cadaveric bone is used, it is typically possible to obtain information through family members of the deceased as to the health or otherwise of the donor. Known screening methods, including PCR, antibody testing, ELIZA assays and the like may all be employed to rule out pathologic contamination of the donor bone tissue. Any method known in the art for sterilization of implants may be utilized, so long as the structural integrity of the implant is not compromised. The conical, wedge-shaped, trocar or other sharp or pointed head portion **20** is machined using a lathe, a computer numerically controlled (CNC) lathe, mill, or both, or like machining devices, as is the cylindrical portion **30**. The suture canal **40** is drilled through the

implant while the channel **41** is machined using the equivalent of a carpenter's lathe. Preferably, the entire suture spear is fashioned from a single piece of bone, although the implant may also be fashioned from, for example, a cylindrical portion which is inserted into a pointed forward section, either by way of a threaded segment on the cylindrical portion, by means of a male-female fit, or any other method of fixation. We have also discovered that it is preferable to machine a piece of bone such that the long axis of the suture spear corresponds with the long axis of the bone from which the suture spear is machined. In this way, the grain of the resulting implant runs with the length of the implant, which, we have found, confers significant strength advantages in the suture spear implant that results. This is particularly true when the suture spear, after machining, is freeze-dried, by lyophilization, sublimation or the like. Freeze-drying of the machined suture spear is a preferred method for preservation and storage of the suture spear.

In figure 2 there is represented a second embodiment **100** of this invention, similar portions of the implant are assigned reference numerals identical to those assigned in figure 1. In this embodiment of the invention, a second canal, **45**, is provided for accepting a second suture strand **55**. This embodiment would be preferred in situations where angular implant fixation to bone is required, or where added security is required, as where a ligament or tendon is being attached to bone under tension or where it is anticipated that the ligament or tendon will experience severe pull-out loads. Preferably, the first canal **40** and, if present, the second canal **45** are configured such that if desired one or more sutures may be passed therethrough. This is facilitated when the canal is oval in shape. It is also desirable for the canal to have radiused edges, such that chaffing and possible cutting of suture strands is minimized. Preferably, the long axis of the oval matches the long axis of the suture spear, such that the grain of the bone goes with the long axis of the oval for strength considerations.

In a further embodiment **200** of this invention, shown in figure 3, the implant of this invention is provided with a barb as an additional retention means **210** in the form of a discontinuous skirt with a channel **220** to permit the tails of the suture **50** to be held in close proximity to the implant **200** when it is being inserted into

recipient bone. The channel also facilitates suture slide to aid the surgeon in tying off of suture ends and to facilitate proper placement of desired suture lengths. In this embodiment of the invention, the retention means **210** is formed during the machining process, such that a piece of bone of an initial diameter greater than the greatest diameter of the head portion **20** and said additional retention means **210** is machined to form the tapered head **20** and additional retention means **210**, such as on a lathe. In yet a further embodiment **300** of this invention, shown in figure 4, the implant is identical to that shown in figure 3, except that a second canal **45** is provided, to permit fixation of a second suture thread.

In figure 5, a further embodiment of the implant of this invention **400** is shown, with a thread **410** inscribed onto the external surface of the head portion **20**. In this embodiment, the rear end of said implant **60'** is modified to permit a means for providing torque, such that said threaded head portion **20** may be threaded into an implant site, rather than being impacted into an implant site. The rear end **60'** may be modified to include a slot, such as for torque application by a flat-head driver means; it may be recessed, for torque application by a hexagon shaped driver means, or the like. The rear end **60'** may further be shaped in such a form, such as a square, to permit purchase by a driver means bearing a mating shape to impart torque thereto.

In figure 6, there is shown yet a further embodiment of the implant of this invention, wherein the head portion **20** has inscribed on the external surface thereof two substantially parallel threads **510** and **520**, wherein said threads have different diameters, such that two planes are defined in the external surface of said head portion **20**, namely and external plane **511**, and an internal plane, **512**.

In figure 7, there is shown a further embodiment **600** of the implant of this invention, wherein the head portion **20** of the implant has formed thereon a fluting or slotted arrangement **610**, such that the head **20** of the implant truly resembles a spear, having a plurality of ridges **620** and valleys. Viewed end-on in figure 7C, this configuration appears to have a clover-leaf structure, with the substantially cylindrical rear portion **30** of the implant being visible as a circle. In yet a further

embodiment, the implant head comprises a gradually curving thread pattern which is sufficiently shallow in curvature that the thread does not impede impaction of the implant into recipient bone, but which, upon impaction, imparts a slight rotation to the implant. This is achieved where the shallow helical thread substantially runs along the long axis of the front end of the suture spear. In another variation, a feature is included on one side but not the other of the forward end of the suture spear such that upon insertion, the feature bites into bone, causing the suture spear to cant, and become lodged in recipient bone at an angle offset from a perpendicular entry direction.

In figure 8, there is shown an embodiment of the implant **700** wherein an end portion **710** of the implant has been substantially demineralized; such that said end portion of the implant is flexible, and accommodates a plurality of suture fixation holes **720**. The presence of these holes, which are pre-formed, may facilitate the elimination of the canal **40** in this embodiment of the implant. For implantation, this embodiment of the implant is fitted into an implantation device which may be impacted by transferring the impact to the rear surface **23** of the head of the implant (see figure 9), and thereafter, the flexible end portion **710** is withdrawn from the insertion device and is sutured to the tissue for fixation to bone. The sutures may be installed either prior to or subsequent to impaction of the implant, depending on the length of the flexible end portion extension **710**.

It will be appreciated that the implant suture spear according to this invention may be implanted into a recipient in need thereof by any appropriate means. For example, a device for implanting a cortical bone suture spear preferably comprises: an impact handle connected to a shaft bearing a means for receiving a cortical bone suture spear therein at the end of the shaft opposite the impact handle. The shaft into which the implant is received is either slidably mounted within an external tubular housing, or is a single piece into which the implant is loaded. Where there is an internal and an external shaft, it is preferred for the internal shaft to be unitary with the impact handle, and for the internal shaft and the external shaft to be adjustably mounted. In this fashion, upon impaction of the impact handle with a cortical bone suture spear mounted within the receiving

means, and abutted against a recipient's bone, the cortical bone suture spear is impacted into the recipient's bone. With reference to figures 9A-9C, specific embodiments of such a device are disclosed.

In figure 9A, there is provided one embodiment of an insertion device **800** for impaction into recipient bone of the implant according to this invention. An implant receiving port **810** comprises a cavity **820** formed by the tines **821, 822, 823** of a collett assembly into which the substantially cylindrical rear end **30** of the implant is fitted. The receiving port **810** is formed at the distal end of a slidable shaft **830** which fits inside a housing **840**. At the proximal end of the shaft **830** is an impaction handle **850** which is struck with a hammer or like impaction means, causing the shaft **830** to advance, impacting the suture spear into recipient bone at least the full length of the suture spear, and up to a stop **845** on the housing **840**. In order to secure a loaded suture spear in the implant receiving port **810**, the cavity **820** is reduced in size by threading the handle **850** on threads **855** which mate between the outer shaft **840** and the inner shaft **830**. Turning the handle in a first direction, which may be clockwise or counter-clockwise, causes the inner shaft **830** to retract into the outer shaft **840**, causing the tines **821, 822, 823** of the collett assembly to be forced together, around the base **30** of the implant. After impaction, the rear end **30** of the implant is released by turning the handle **850** the opposite direction, thereby allowing the tines **821, 822, 823** of the collett assembly to emerge from the outer shaft **840**. A similar result may be achieved by other means, such as, for example, a simple two position stop system, wherein, in a first stop position, the inner shaft is fully extended, and the tines **821, 822, 823** of the collett assembly extend from the end of the outer shaft **840** for implant loading or release after impaction, while in a second retention position, the tines **821, 822, 823** of the collett assembly are drawn into the outer shaft **840**, which results in secure grip on the based **30** of the implant. It will be appreciated that the diameter of the outer shaft **840** of the insertion device **800** should be sufficiently small to facilitate navigation of the suture spear loaded into the implant receiving port to a desired location, even in an arthroscopic or laproscopic procedure. In figure 9B, the implant apparatus is shown with a suture spear mounted therein, in readiness for impaction implantation.

In figure 9C, an alternate embodiment of the loading device **800** is shown wherein the implant receiving port is simply a pair of tines **860**, between which an implant is located. The tine ends **861** abut the rear surface **23** of the implant, such that upon impaction, the implant is driven into recipient bone. This embodiment of the loading device **800** is preferred for implantation of embodiments of this invention, such as that shown in figure 8, since the flexible implant portion **710** is simply situated between the tines **861**. It will be appreciated that the tines of the implant loading device **800** may form a complete circle around the implant end portion **30**, thereby maximizing protection of that portion of the implant during implantation thereof.

In figure 10, there is shown a further embodiment **900** of the implant of this invention wherein a flange **910** is included as the base of the implant. The flange **910** or rear surface **23** of the point **20** may further comprise barbs **920**. In this embodiment of the implant, a piece of soft tissue **940** may be interposed between the implant point **20** and recipient bone **930** upon implantation. As the implant penetrates the soft tissue **940**, the flange **910** forms a retention means for the penetrated tissue, essentially tacking the tissue to recipient bone **930** into which the implant **900** is impacted. The barbs **920**, if present, assist in gripping of the soft tissue by the implant. In yet a further embodiment, the flange **910** may be demineralized at the terminal ends thereof, providing an additional or exclusive site for suture fixation. Tissue **950** is affixed to the suture spear **900** and bone **930**, into which the suture spear is impacted, by means of sutures.

In figure 11A, there is shown a schematic view of one embodiment of the suture spear of this invention. In figure 11B, there is shown a rear view of the suture spear, viewed from the rear of the suture spear cylindrical body toward the pointed head. Specific dimensions in millimeters are provided as suggestive of acceptable or preferred dimensions and tolerances, although it will be appreciated that this invention is not limited to these specifics. In figure 11C, there is shown a side view of this embodiment of the sutures spear, again with specific tolerances and dimensions shown in millimeters, as exemplary written description of this

embodiment of the invention. In figure 11D, there is shown a side view of this embodiment of the suture spear, rotated ninety degrees as compared with the view shown in figure 11C, with further specific dimensions shown as suggestive and to complete the written description of this implant. The point **1000** may have a 0.125 maximum point radius, or it may have a 0.5 mm maximum blunt end. It will be appreciated that for all of these dimensions and tolerances, some variations may be permitted, for various embodiments of this invention, without departing from the essential features of this invention.

Suture spears prepared according to the foregoing disclosure have been implanted into humerus by direct impaction without the need for tapping or threading of the recipient humerus. We have found, surprisingly, that the suture spears thus implanted have a pull-out strength which is at least equivalent to the strength of number two suture. Accordingly, based on these tests, we anticipate the suture spear of this invention to be fully functional clinically, since the pull-out strength of the spears is at least as great as the failure load of commonly used sutures. Where the suture spear of this invention is to be implanted into particularly dense cortical bone, as in, for example, the glenoid rim, it is preferred to use an awl to puncture a hole into which the suture spear may subsequently be impacted. Alternatively, a tapped hole may be created in the recipient bone, and a threaded embodiment of the suture spear carefully torqued into the tapped hole. Surprisingly, we have found that the pull out strength and insertion survival of cortical bone suture spears of this invention is greater when the suture spear is impacted into recipient bone, as opposed to threaded insertion of the suture spear.

In view of the foregoing disclosure, it will be appreciated that this invention disclosure is directed to a cortical bone suture spear, which preferably comprises a pointed head portion, a substantially cylindrical body portion, and a first canal for receiving a suture therethrough. It will be appreciated that a substantially cylindrical portion includes perfectly cylindrical body portions, body portions that are not perfectly cylindrical and body portions having, for example, multiple faces, as in an hexagonal, octagonal or like geometric shape. It is also conceivable that the body portion would be triangular in cross section, and such

variation should not be considered to be outside the scope of the instant disclosure. In one embodiment, the head portion is substantially conical. In certain embodiments, the cylindrical body portion comprises a second canal for receiving a second suture therethrough. Preferably, for strength considerations, where a second suture canal is present, the second canal is substantially oriented at ninety degrees to the orientation of the first canal. Furthermore, in some embodiments of this invention, it is preferred for the cylindrical body portion to comprise, in addition to the head portion having a diameter greater than that of the cylindrical portion, an additional retention means in the form of a barb of cortical bone. The maximum diameter of the barb and of the conical head may be the same or different. Thus, the head maximum diameter may be greater or smaller than that of the barb.

In certain embodiments of the suture spear of this invention, it is preferred for the pointed head portion to have an external feature inscribed therein in the form of a helical screw thread. In this event, it is preferred for the body portion to include a means for applying torque for insertion of the helical screw thread, although in certain preferred embodiments, where a relatively gradual helical thread is inscribed into the head portion, the suture spear bearing such an external feature is impact driven into recipient bone with great success, enhanced pull-out strength, and reduced insertion resistance, at least in part due to the ability to form sharp edges to such threads, thereby reducing frictional drag upon insertion of the suture spear bearing this feature. In one embodiment, the pointed head portion has external features inscribed therein in the form of a first thread and a second thread, wherein the first and second threads are substantially parallel, but wherein the first thread has a different diameter than the second thread at any specific point along the pointed head portion.

In some embodiments of the suture spear of this invention, a portion thereof is preferably partially or completely demineralized. In one such embodiment, the conical suture spear head portion is partially demineralized at the largest diameter circumference of conical head portion. In another such embodiment, the

substantially conical suture spear head portion is partially demineralized to form a hinge portion between adjacent sides of the conical head portion.

In practice, we have found that the suture spear of this invention is preferably between about 5 and about 20 mm long. Most preferably, the suture spear is between about 8 and about 15 mm long. In addition, the suture spear conical head portion preferably tapers to a point from a maximum diameter of between about 1 mm to about 10 mm, and most preferably, from a maximum diameter of between about 2.5 mm to about 7 mm, or 3 mm to about 5 mm.

It will further be appreciated, in light of the foregoing disclosure, that this invention comprises a method of fixing tissue to bone which comprises suturing such tissue to a cortical bone suture spear. This method is useful in such procedures as repair of rotator cuff injuries in the shoulder, reattachment of tissue at the rim of the glenoid socket, repair of slap lesions, Bankhardt procedures, in ACL or other ligament repair, or any other medical procedure in which it is desirable to attach or re-attach tissue to bone. The invention further comprises a method of making a suture spear which comprises harvesting a segment of cortical bone, machining the cortical bone to form said suture spear comprising a pointed head portion, a cylindrical body portion, and a first canal for receiving a suture therethrough. Machining of an additional retention barb, additional suture canals, threads and other features as disclosed and suggested herein also come within the scope of this invention and the claims appended hereto.

In yet a further embodiment of this invention, a suture spear having a rounded head is prepared from cortical bone on a CNC lathe or the like, preferably having a fourth floating axis for a ball and end mill. This embodiment of the suture spear may have one or more through canals for receiving one or more suture threads. Alternatively, in an embodiment shown in Figure 12A, which shows a perspective view of a further embodiment of the suture spear of this invention having a rounded tip and an inscribed groove, rather than or in addition to a through canal. In Figure 12A, the suture spear **1200** has a rounded head portion **1210**, a collar portion **1220**, and a rear portion **1230**. Inscribed into the suture spear **1200** is a

suture groove **1240** which starts at one side of the rear portion **1230** and proceeds anteriorly toward and over the rounded head portion **1210** and down an opposite side of suture spear **1200** toward the rear portion **1230**. The depth and width of the suture groove **1240** is preferably maintained at a constant level sufficient to accommodate a suture within the groove along the rear portion **1230**, the collar portion **1220** and the rounded head portion **1210**, except that, as shown in figure 12C below, preferably, at the very apex of the head **1210**, the suture is retained in a slightly deeper notch **1241**.

Figure 12B shows a cross-sectional side view of the suture spear shown in figure 12A along line A-A in figure 12C. Like parts are numbered as in figure 12A, but also shown in cross-section is a partial cannulation **1250** for insertion of the tip of a suture-spear insertion device. Also shown is the solid, preferably flush rear surface **1231** of the rear end **1230** of the suture spear **1200** which abuts the end of the insertion device upon application of the suture spear onto the inserter.

Figure 12C shows an external side view with optional dimensions in millimeters for one embodiment of the suture spear shown in figure 12A. It will be understood that these dimensions are suggestive only and that variations and modifications of these dimensions may be required, depending on the suture-anchoring operation required and the nature of the implant site. For clarity, parts of this view are not labeled as in figures 12A and 12B, except that at the very apex of the head **1210**, the suture is retained in a slightly deeper notch **1241**. Also shown in this view is a slight narrowing **1242** of the suture groove **1240** right at the apex of the rounded head **1210**, due to leaving a slight lip of bone **1242** on either side of the groove. This slight lip **1242** on either side of the suture groove **1240** assists in retention and loading of the suture onto the spear, which preferably is already mounted on an inserter.

Figure 12D shows an end-on frontal view of the rounded tip of the suture spear shown in figure 12A. This view emphasizes features of the head **1210** of the suture spear **1200**, including the groove **1240**, the depression **1241**, and the narrowing **1242** in the suture groove at the apex of the head **1210**.

Figure 12E shows a cross-sectional view along line B-B shown in figure 12C viewed toward the rear. This view emphasizes the features of the collar **1220**, including the presence of the central partial cannulation **1250**, and the suture groove **1240**. As can also be seen from this view, the collar has a narrower diameter **1221** as compared to the diameter **1232** of the rear end **1230**. In this manner, as the suture spear **1200** is caused to penetrate into a recipient's bone, upon passage of the head portion **1210** through the cortex of the recipient's bone, the rear end **1230** may act as a stop to prevent further penetration, and the cortex of the recipient's bone "springs-back" and retains the suture spear **1200** at the collar region **1220**. Alternatively, the suture spear may be completely buried in the recipient's bone, and the narrower collar region **1220** facilitates traversal of the broader rear end **1230**, which upon penetration into the cortex of the recipient's bone, acts as a stop to extrusion of the anchor via the flush rear surface **1231** abutting the inside surface of the patient's cortical bone.

Figure 12F shows an end-on rear view of the insertion hole and rear end of the suture spear shown in figure 12A. Emphasized in this view is the rear end **1230** of the suture spear, showing the flush rear surface **1231** of the rear end **1230**, the instrument attachment hole **1250**, and the suture groove, **1240**.

In a further embodiment of the suture spear **1200** of this invention, the suture spear may have a second suture groove **1240'** inscribed at a location spaced apart on the body of the suture spear **1200** such that the groove **1240** and the groove **1240'** intersect at right angles on the head **1210** of the suture spear **1200**. In addition, the suture spear may comprise one or more through canals. Such modifications may be employed for procedures requiring multiple suture lines. In addition, it will be appreciated that the suture grooves **1240** and **1240'**, if present, accommodate required movement and sliding of the suture by the surgeon within the groove, thus facilitating formation of required knots and the like at the distal end of the suture.

Figure 13A shows an external side view of one embodiment of an insertion device **1300** for the suture spear shown in figure 12A. As can be seen, the inserter **1300** has a front tip **1310** for insertion into the partial cannulation **1250** in the rear end **1230** of the suture spear **1200**. The diameter of the tip **1310** should be precisely matched to the diameter of the partial cannulation **1250** so that a tight fit between the inserter **1300** and suture spear **1200** occurs upon installation of the suture spear on the inserter. To provide maximal strength to the inserter, the shaft **1305** of the instrument comprises sections **1320** and **1330** of increasing diameters. Naturally, those skilled in the art will appreciate based on this disclosure that modifications on this arrangement may be made without destroying the operative principles of the device. At the distal end of the inserter, there is provided a handle **1340** which has a distal end **1341**. In one embodiment, the distal end **1341** of the handle **1340** is a flush surface which may be impacted with a mallet, hammer or like impeller means. In this manner, a suture spear **1200** loaded on the tip **1310** of the inserter **1300** may be induced to perforate the cortical surface of a recipient's bone. Since a suture loaded on the suture spear **1200** is protected within the suture groove **1240** the insertion of the suture spear firmly seats the suture within the recipient's bone, as disclosed for other embodiments of the suture spear disclosed herein.

Figure 13B shows a cross-sectional side view of the insertion device **1300** shown in figure 13A along section line A-A. In this embodiment of the insertion device **1300'**, within the handle **1340'**, there is disposed a means for cushioning, integrating or otherwise averaging an impact applied to surface **1341'**. In the embodiment diagrammed in figure 13B, there is provided a dampening means in the form of a spring **1342**, which rides at the head of a piston **1343** attached to the head **1344** of the shaft **1305**. The piston **1343** slidably rides within a cylindrical housing which forms the handle **1340'**. Upon impaction of the surface **1341'**, the impact energy is absorbed by the spring **1342** which then conveys the energy to the piston **1343** to drive in a significantly more smooth fashion the penetration of the suture spear **1200** into a recipient's bone. (See figure 15). In an alternative to this embodiment, the insertion device **1300** is a push impactor, with a mechanism such as is known in the art for such a device, such that upon application of a

steady force to the handle **1340**, a compressive force is stored within the handle and at a pre-determined load, is released, to deliver a known, metered force to the shaft **1305** of the inserter **1300**. In yet a further embodiment, the inserter comprises both a damping spring **1342** and means for providing a push impactor. In this fashion, use of a hammer, mallet or the like is not required, as the surgeon or other operator of the inserter applies force to the handle **1340** and at a pre-determined load, the inserter fires, causing advancement of the shaft **1305**. However, in this embodiment, the damping spring **1342** averages out the metered force over time to provide for smooth insertion of the suture spear **1200**. To minimize the force required for the suture spear **1200** to penetrate a recipient's bone, preferably an implant hole is first drilled, fashioned with an awl, spike or the like. Preferably, the hole has a diameter smaller than the largest diameter of the head **1210** of the suture spear **1200**. In this fashion, upon penetration of the suture spear into the recipient's bone, a tight fit occurs without splitting the recipient's bone. In addition, traversal of the rear end **1230** of the suture spear **1200** into the recipient's bone is ensured to create a firm fixation of the suture spear in the implant site.

Figure 14 shows the suture spear **1200** of figure 12A mounted on the tip **1310** of the insertion device **1300** of figure 13A, with a suture **1400** mounted thereon and a retainer sleeve **1410** mounted on the shaft of the insertion device, over the suture. As can be seen, the suture **1400** is placed within the groove **1240** of the suture spear **1200** and is retained within the tip **1210** of the suture spear, inside a preferred depression **1241**, if present. The retainer sleeve **1410** is preferably mounted over the suture spear **1200** and the suture **1400** mounted on the tip **1310** of the inserter **1300**. The suture **1400** is thus maintained in a taught condition as shown by suture outline **1400'**, and held by the surgeon holding the handle **1340**. Subsequent to insertion of the suture spear **1200** into the implant site, the suture is allowed to slide free from the retainer sleeve **1410** and the inserter **1300** is removed from the suture spear. A further optional feature of the retainer sleeve, which may be made from clear, sterile plastic, metal or any other sterile material, is the positioning of the proximal end **1415** of the retainer sleeve **1410** such that upon impaction of the inserter device **1300**, the proximal end **1415** of the retainer

sleeve **1410** acts as a stop against the surface of the recipient's bone, to prevent excess penetration of the suture spear **1200** or the inserter **1300**.

Having generally described this invention with respect to the method of making and using the suture spear of this invention, including the best mode thereof, the scope of legal protection in which exclusive rights is claimed herein is defined by the claims, and equivalents thereof, which are appended hereto.

EXAMPLES:

EXAMPLE 1

Insertional loading and test results of RTI Grooved internal drive suture spear

Forty-two suture spears from from three different donors were manufactured to the specifications as described in Figure 12A. The anchors were lyophilzed and tested for insertion and pullout in the glenoid rim and rotator cuff locations. SpiderWire with 60lbs of tensile strength was utilized instead of metallic cable for pullout testing. Table 1 and 2 describe the results from all of the tests.

Results - *Rotator Cuff*

All anchors were successfully inserted in the rotator cuff location. However, one of the anchors failed during insertion. This unsuccessful insertion attempt was attributed to the instability of the femur while impact loads were being applied. In order to insert an anchor in the simulated rotator cuff location in a pig femur. It required an average of 22 hits (Range: 7-49) between 52—1000+ lbf of impact on the inserter. All anchors recorded pullout loads above 112.5N. However, three anchors were noted to pullout below 112.5N. All three of these anchors were in the same pig femur which upon closer examination revealed poor quality low density cancellous bone. Two of the anchors were reinstalled in a different location and recorded pullout loads well above 112.5N. Excluding the data points below 112.5N, the average pullout loads were 174N (Range 116-225N, n=17). Many of the anchors failed by pullout and appeared intact, however several were observed after pullout to have broken midshaft. In addition, failure also occurred by the spiderwire failing at the knot or untieing. This occurred well above 112.5N.

Results - *Glenoid Rim*

All anchors were successfully inserted in the glenoid rim location. However, three of the anchors failed and this was attributed to the fact that the pig femur was not secure in the vice in which it was being held. The unsuccessful insertion attempt was attributed to the instability of the femur while impact loads were being applied. In order to insert an anchor in the simulated glenoid rim location in a pig femur. It required an average of 23 hits (Range: 7-57) between 52—1000+ lbf of impact on the inserter. The average pullout loads was 189N (Range 133-282N, n=18). Many of the anchors failed by pullout and appeared intact, however several were observed after pullout to have broken midshaft. In addition, failure also occurred by the spiderwire failing at the knot or untieing. This occurred well above 112.5N. **Conclusion:** The anchors in the current design meet the acceptance criteria.

EXAMPLE 2

Biomechanical Evaluation of a Novel Allograft Suture Anchor

The use of allograft bone has significantly expanded over the past few years as a direct result of the development of precision processing technologies. For example, precision machined allograft dowels, interference screws, and pins have recently been introduced into the surgical community. Other potential applications are as a suture anchor, which secures a suture line into a bony substrate. However, in order for these implants to be widely accepted, they must be convenient for the user, successfully withstand insertion loading, and have high resistance to pullout.

Freeze-drying is a common and convenient method for storage of allografts. However, this process makes bone brittle and could impart unacceptable consequences on products that are maintained in such a state. If these mechanisms are understood, products may be properly designed in order to overcome these deficiencies.

The objectives of this study are to describe a novel allograft suture anchor composed entirely of freeze-dried cortical bone, as well as to present our results on the biomechancs of insertion and its resistance to pullout.

MATERIALS AND METHODS

Cortical bone from three donors was procured, machined into 35 suture anchors and lyopholized. Specimens from each donor were randomly chosen and placed into two different insertion sites: a glenoid rim location and rotator cuff location. SpiderWire™ (Johnson Worldwide Associates, Inc; Stuartevant, WI) with a tensile strength of 240N was utilized in lieu of #2 suture (USP tensile strength 70N) so that the failure would occur by anchor pullout rather than suture breakage.

The porcine femoral head, which is representative of a 50 year old male, was used for the implantation of the suture anchors. The intact femoral head represented the glenoid rim location while a trough cut into the femoral head, which removed the cortical bone surface, represented the rotator cuff location. An awl created a 3.0mm hole for insertion of the anchor. The suture anchor was inserted into the site with specially designed instruments and a surgical mallet. The mallet was equipped with a 1000lbf-impact load cell (PCB Piezotronics Depey, NY) which was attached to an oscilloscope to record the maximum impact load and the number of hits to insert the anchor approximately 3mm below the surface of the insertion site.

Pullout loads were determined on the MTS Bionix 858 servohydraulic mechanical test apparatus. The porcine femur was pinned underneath a plate and the Spiderwire™ looped around a hook and pulled parallel to the tunnel. Load applied at the rate of 12.5mm/sec and the maximum load and type of failure recorded. These methodologies were adapted from descriptions in the literature.

RESULTS AND DISCUSSION

All suture anchors were successfully implanted into the rotator cuff (n=17) and glenoid rim (n=18) locations. Insertion requirements for the rotator cuff and glenoid rim locations were an average of 22 hits (range: 7-49) and 23 hits (range: 7-57) respectively with the impact loads between 52 - 1,000+ lbf. The pullout loads were 174N (range: 116-225N) and 189N (range: 133 - 282N) for the rotator cuff and glenoid rim location respectively.

CONCLUSIONS

Allograft suture anchors may be designed with sufficient strength to exceed insertional loading requirements as well as provide pullout resistance comparable to synthetic anchors and well above the USP strength of #2 suture.

WHAT IS CLAIMED IS:

1. A cortical bone suture spear.

2. The suture spear according to claim 1 comprising a pointed head portion, a substantially cylindrical body portion, and a first canal for receiving at least one suture therethrough.

3. The suture spear according to claim 2 wherein said head portion is substantially conical, trocar shaped, or wedge shaped

4. The suture spear according to claim 3 wherein said cylindrical body portion comprises a second canal for receiving a second suture therethrough.

5. The suture spear according to claim 4 wherein said second canal is substantially oriented at ninety degrees to the orientation of said first canal.

6. The suture spear according to claim 2 wherein said cylindrical body portion comprises, in addition to said head portion, an additional retention means in the form of a barb of cortical bone.

7. The suture spear according to claim 2 wherein said pointed head portion is substantially conical.

8. The suture spear according to claim 7 wherein said pointed head portion, said cylindrical portion or both, has an external feature inscribed therein in the form of a helical screw thread, and wherein said body portion has a means for applying torque for insertion of said helical screw thread or impaction insertion thereof.

9. The suture spear according to claim 7 wherein said pointed head portion has external features inscribed therein in the form of a first thread and a second thread, wherein said first and said second threads are substantially parallel, but

wherein said first thread has a different diameter than said second thread at any specific point along said pointed head portion, and wherein said body portion has a means for applying torque or impaction for insertion of said helical screw thread.

10. The suture spear according to claim 7 wherein said pointed head portion has external features inscribed therein in the form of a first thread and a second thread, wherein said first and said second threads are substantially parallel, but out of phase with each other by approximately one half turn, and wherein the axes about which said first thread and said second thread translate are on either side of the central axis of the suture spear.

11. The suture spear according to claim 2 wherein a portion thereof is partially or completely demineralized.

12. The suture spear according to claim 3 wherein a portion of said substantially conical suture spear head portion is partially demineralized at the largest diameter circumference of said conical head portion.

13. The suture spear according to claim 3 wherein a portion of said substantially conical suture spear head portion is partially demineralized to form a hinge portion between adjacent sides of said conical head portion.

14. The suture spear according to claim 2 wherein said suture spear is between about 5 and about 20 mm long.

15. The suture spear according to claim 14 wherein said suture spear is between about 8 and about 15 mm long.

16. The suture spear according to claim 2 wherein said suture spear conical head portion tapers to a point from a maximum diameter of between about 1 mm to about 10 mm.

17. The suture spear according to claim 16 wherein said suture spear conical head portion tapers to a point from a maximum diameter of between about 2.5 mm to about 7 mm or about 3 mm to about 5 mm.

18. The suture spear according to claim 1 wherein the longitudinal axis of said suture spear corresponds to the longitudinal axis of a source bone from which said suture spear is machined.

19. The suture spear according to claim 1 wherein said suture spear is freeze-dried.

20. The suture spear according to claim 10 wherein said partially or completely demineralized portion of said suture spear has suture holes formed therein for threading of sutures therethrough.

21. The suture spear according to claim 2 wherein said cylindrical body portion terminates in a flange.

22. The suture spear according to claim 21 wherein said flange comprises a barb.

23. The suture spear according to claim 2 wherein said first canal is substantially oval in shape.

24. The suture spear according to claim 4 wherein said second canal is substantially oval in shape.

25. The suture spear according to claim 1 wherein said suture spear comprises at least one suture-receiving canal running therethrough wherein said at least one suture-receiving canal has a trailing edge facing away from the pointed end of the suture spear which tapers to the full diameter of a cylindrical portion of the suture spear, thus forming a channel within which a suture strand slidably rides and is protected against fraying by bone upon insertion.

26. The suture spear according to claim 23 wherein the long axis of the oval canal corresponds with the long axis of the suture spear.

27. A method of fixing tissue to bone which comprises suturing said tissue to a cortical bone suture spear.

28. The method according to claim 27 wherein said suture spear comprises a pointed head portion, a substantially cylindrical body portion, and a first canal for receiving a suture therethrough.

29. The method according to claim 28 wherein said cylindrical body portion comprises a terminal end away from said pointed head portion which is partially or completely demineralized and through which sutures are threaded.

30. The method according to claim 29 wherein said cylindrical body portion comprises a terminal end away from said pointed head portion in the form of a flange, which grips tissue through which said pointed head portion passes while being implanted into recipient bone.

31. A method of making a suture spear which comprises harvesting a segment of cortical bone, machining the cortical bone to form said suture spear comprising a pointed head portion, a substantially cylindrical body portion, and a first canal for receiving a suture therethrough.

32. A device for implanting a cortical bone suture spear which comprises an impact handle connected to a shaft bearing a means for receiving a cortical bone suture spear therein at the end of said shaft opposite said impact handle, wherein said shaft is slidably mounted within an external tubular housing to which said impact handle is adjustably mounted, such that upon impaction of said impact handle with a cortical bone suture spear mounted within said receiving means, and abutted against a recipient's bone, said cortical bone suture spear is impacted into said recipient's bone.

33. The suture spear according to claim 1 having a rounded head.

34. The suture spear according to claim 33 prepared from cortical bone on a CNC lathe.

35. The suture spear according to claim 1 comprising a rounded head portion, collar portion, a rear portion and a groove inscribed in said suture spear.

36. The suture spear according to claim 35 wherein said groove starts at one side of said rear portion and proceeds anteriorly toward and over said rounded head portion and down another side of said suture spear.

37. The suture spear according to claim 35 wherein said groove is of a depth and width to accommodate a suture.

38. The suture spear according to claim 37 wherein said groove is deeper at the rounded head portion than other portions of said suture spear.

39. The suture spear according to claim 38 wherein said groove is narrower at the apex of said rounded head portion than at other locations along said groove.

40. The suture spear according to claim 1 wherein said suture spear is partially or fully cannulated.

41. The suture spear according to claim 1 wherein said collar portion is smaller in diameter than the rear portion or rounded head portion, or both.

42. The suture spear according to claim 1 wherein said suture spear comprises one or more through channels.

43. A device for inserting a suture spear into a recipient's bone comprising a shaft having a first end and a second end; a tip for engaging said suture spear, said tip

being in rigid attachment to said first end of said shaft; and a handle, said handle being attached to said second end of said shaft.

44. The device of claim 43 wherein said suture spear is partially or fully cannulated and said tip is inserted into said cannulation.

45. The device of claim 43 wherein said handle comprises a housing that encloses a slideable piston, said piston comprising a first end that is in contact with a dampening means and a second end that is attached to said second end of said shaft.

46. The device of claim 43, wherein said handle comprises a means for providing a push impactor, such that a upon application of steady a force to said handle, a compressive force is stored within the handle and, at a predetermined load, is released to deliver a known, returned force to said shaft.

47. A method of fixing an object to bone comprising inserting into said bone a suture spear held in contact with one or more sutures, and attaching said suture to said object.

48. The method of claim 47 wherein said object is tissue.

49. The method of claim 47 further comprising forming an implant hole in said bone for receiving said suture spear, whereby damage to the surrounding bone at the insertion site is decreased.

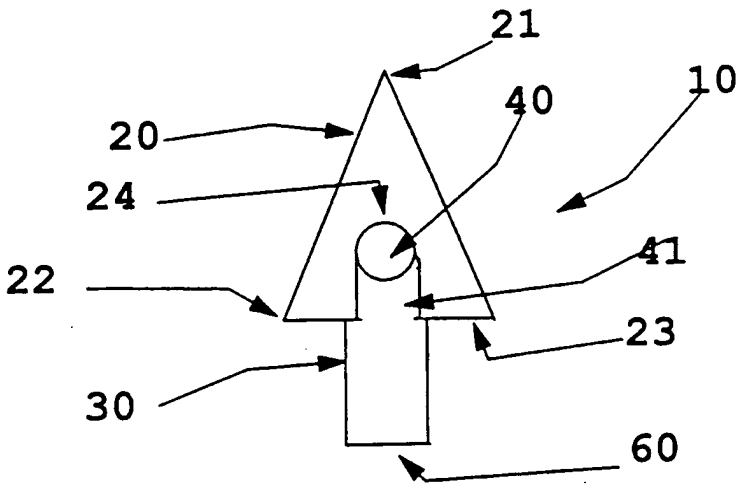

FIGURE 1A

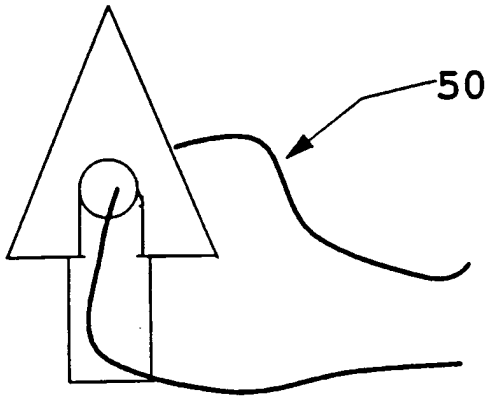

FIGURE 1B

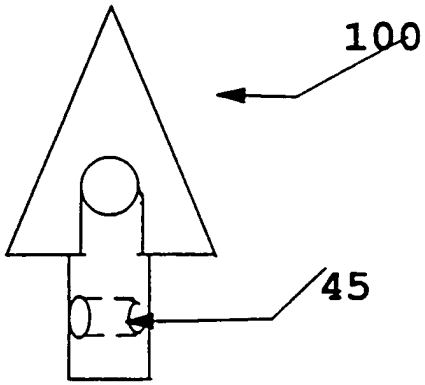

FIGURE 2A

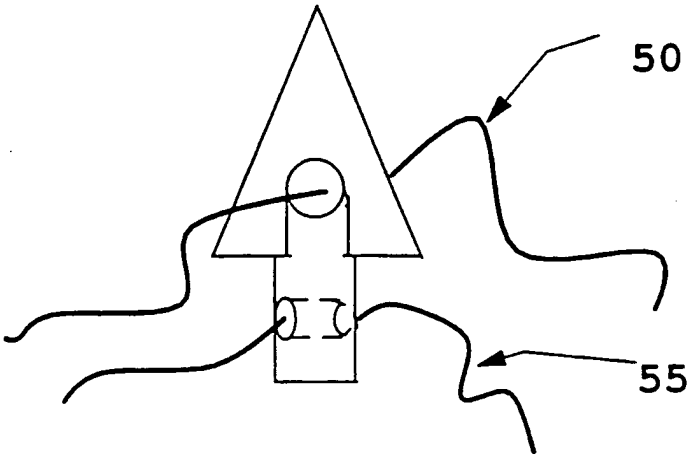

FIGURE 2B

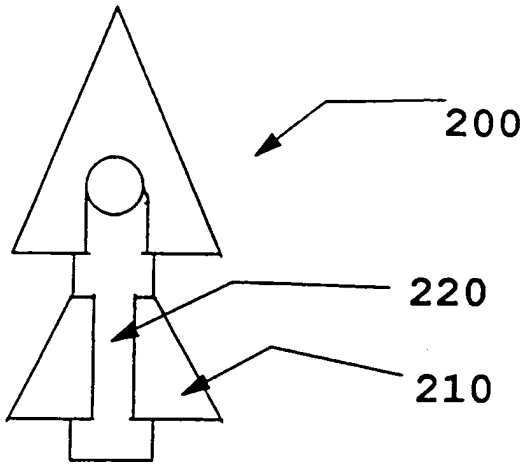

FIGURE 3A

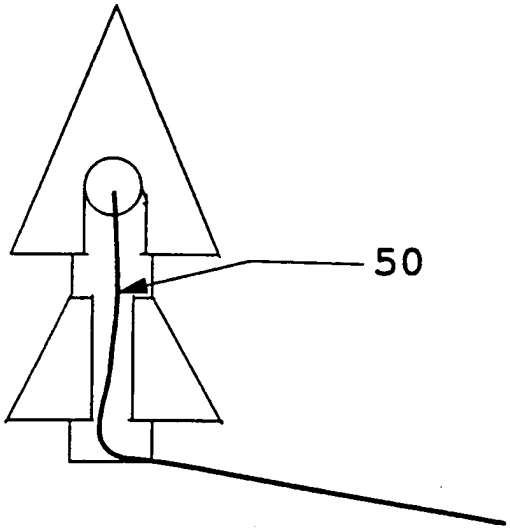

FIGURE 3B

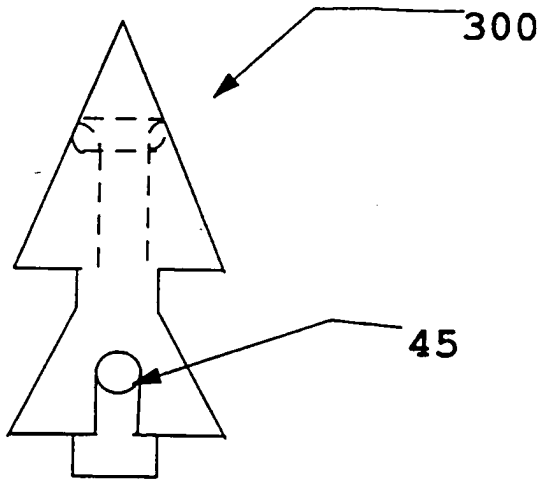

FIGURE 4A

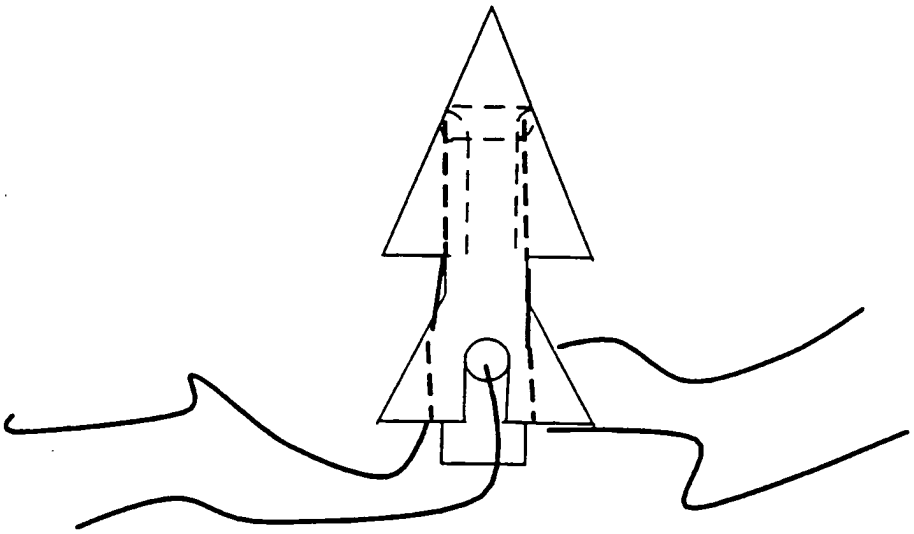

FIGURE 4B

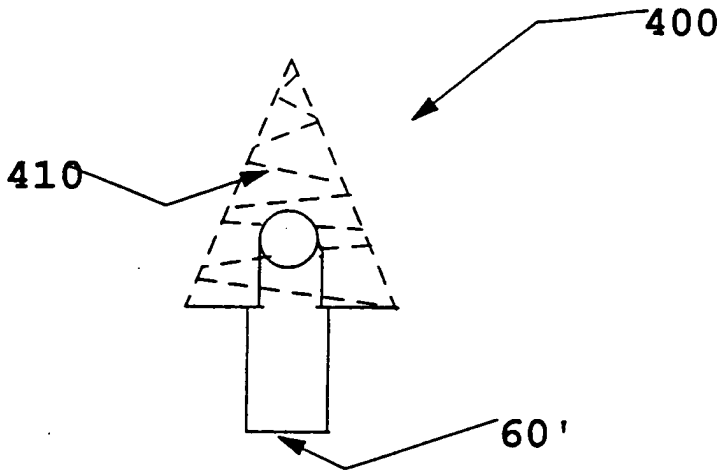

FIGURE 5A

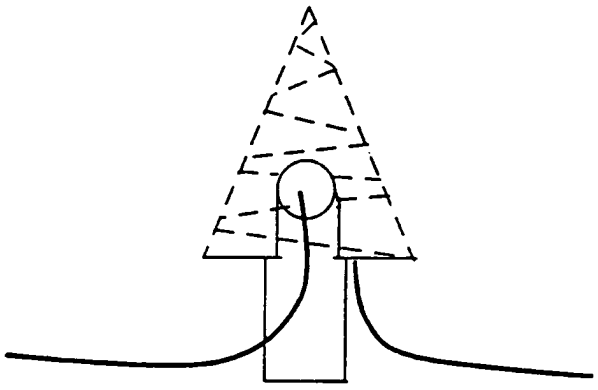

FIGURE 5B

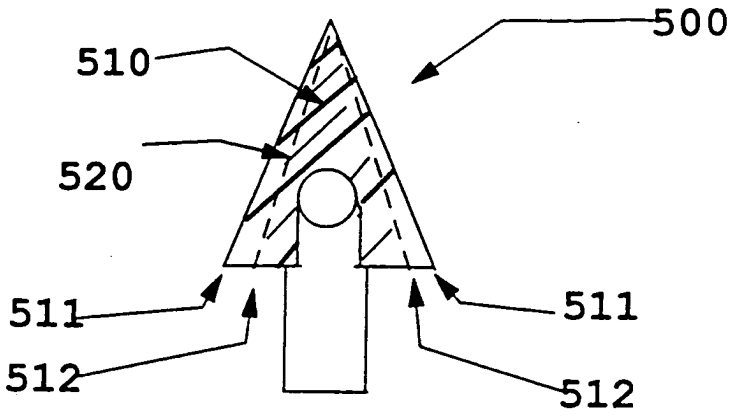

FIGURE 6A

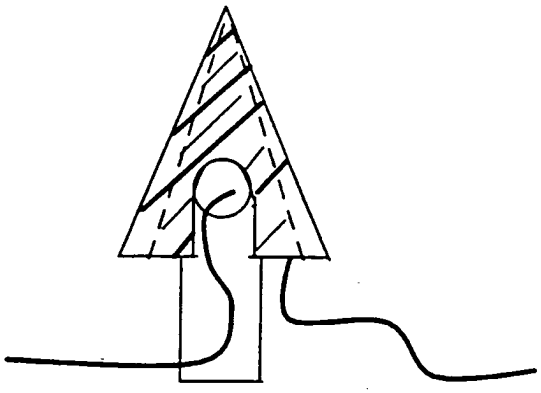

FIGURE 6B

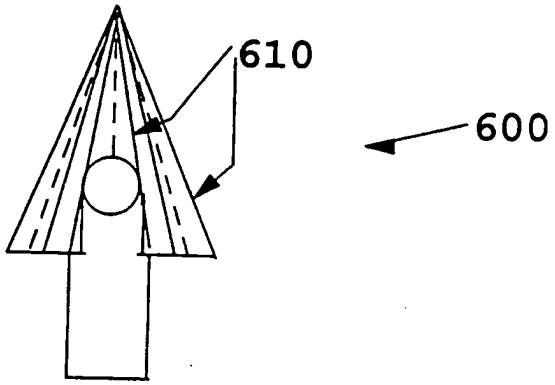

FIGURE 7A

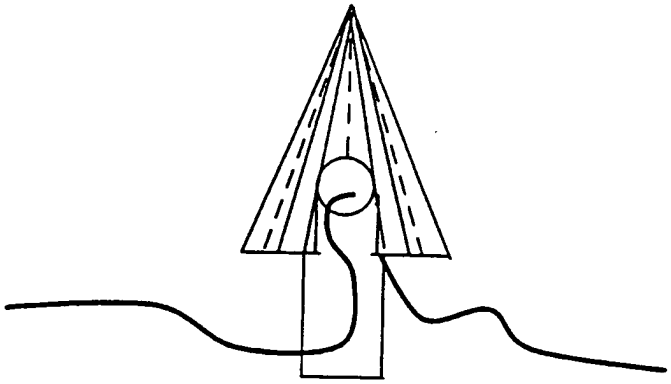

FIGURE 7B

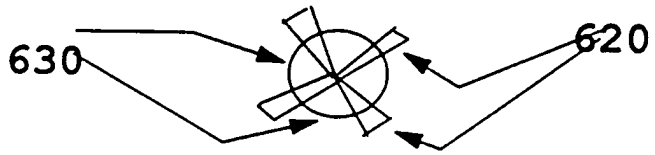

FIGURE 7C

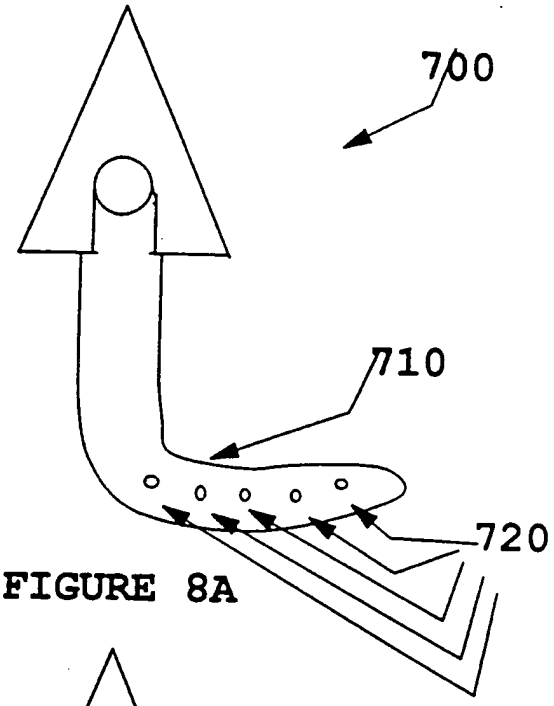

FIGURE 8A

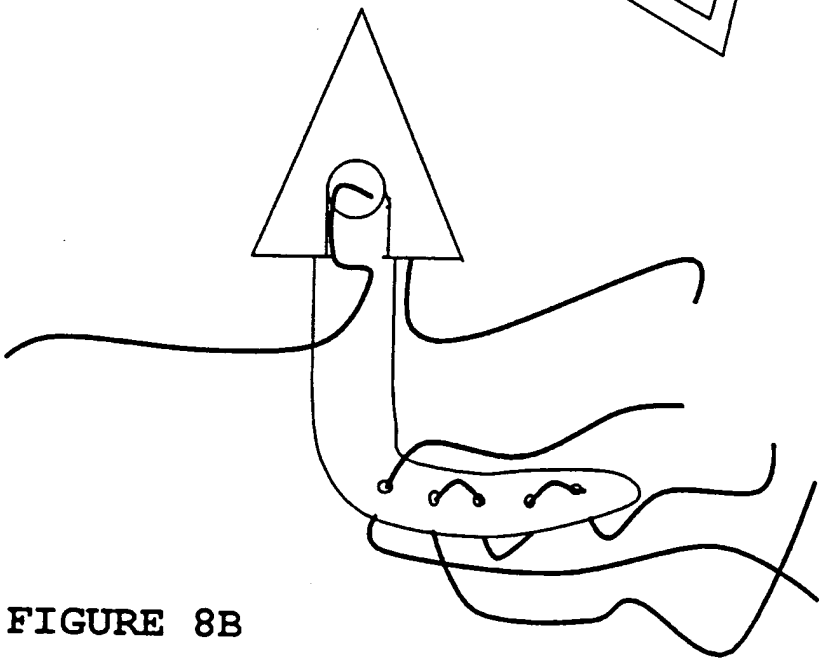

FIGURE 8B

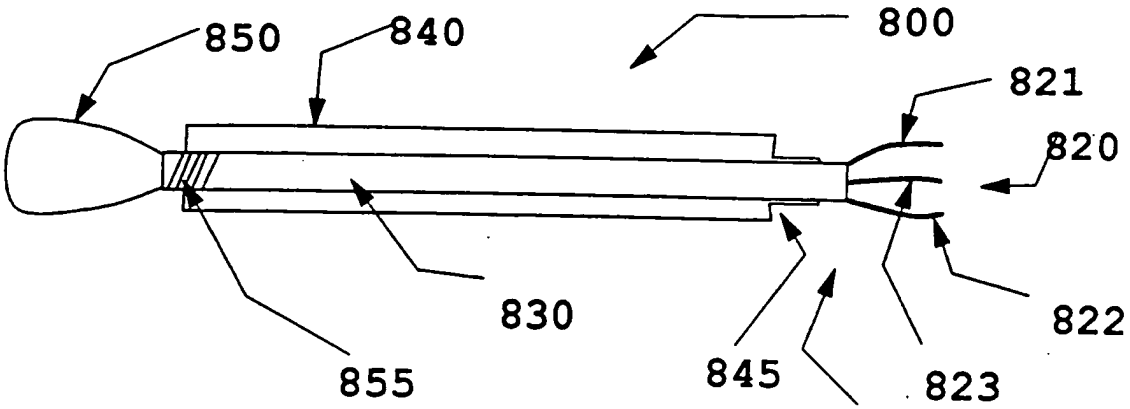

FIGURE 9A

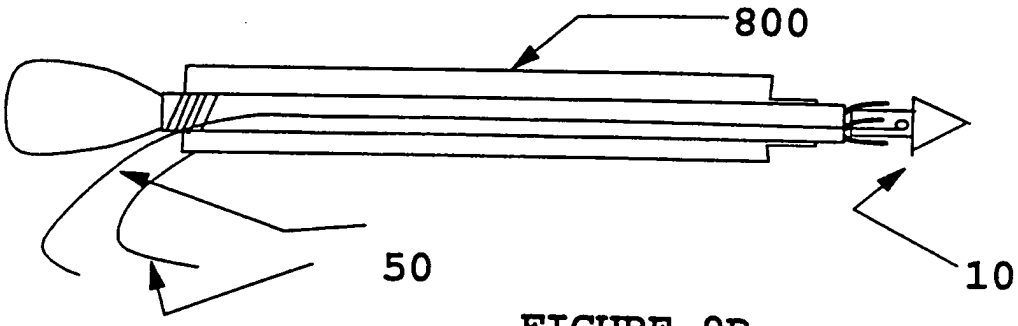

FIGURE 9B

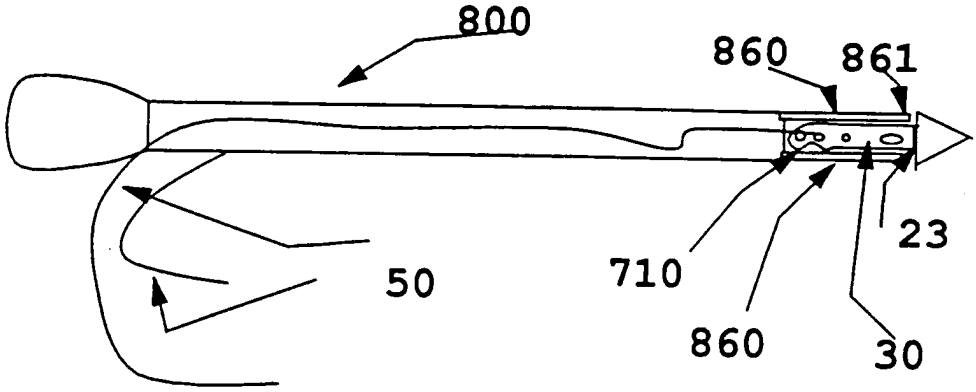

FIGURE 9C

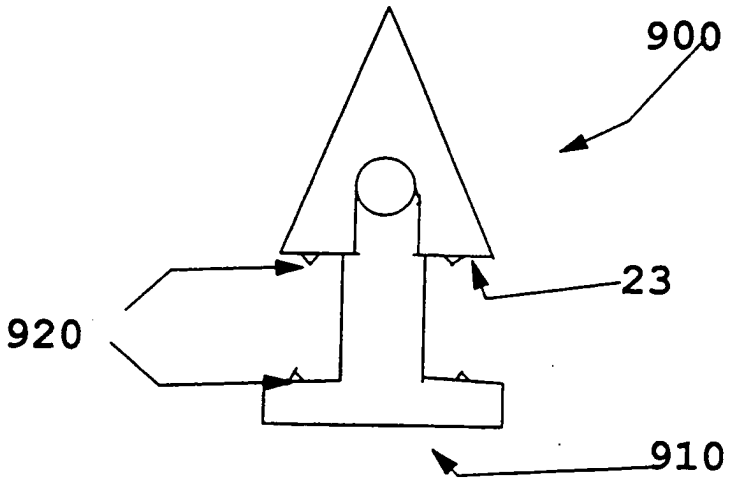

FIGURE 10A

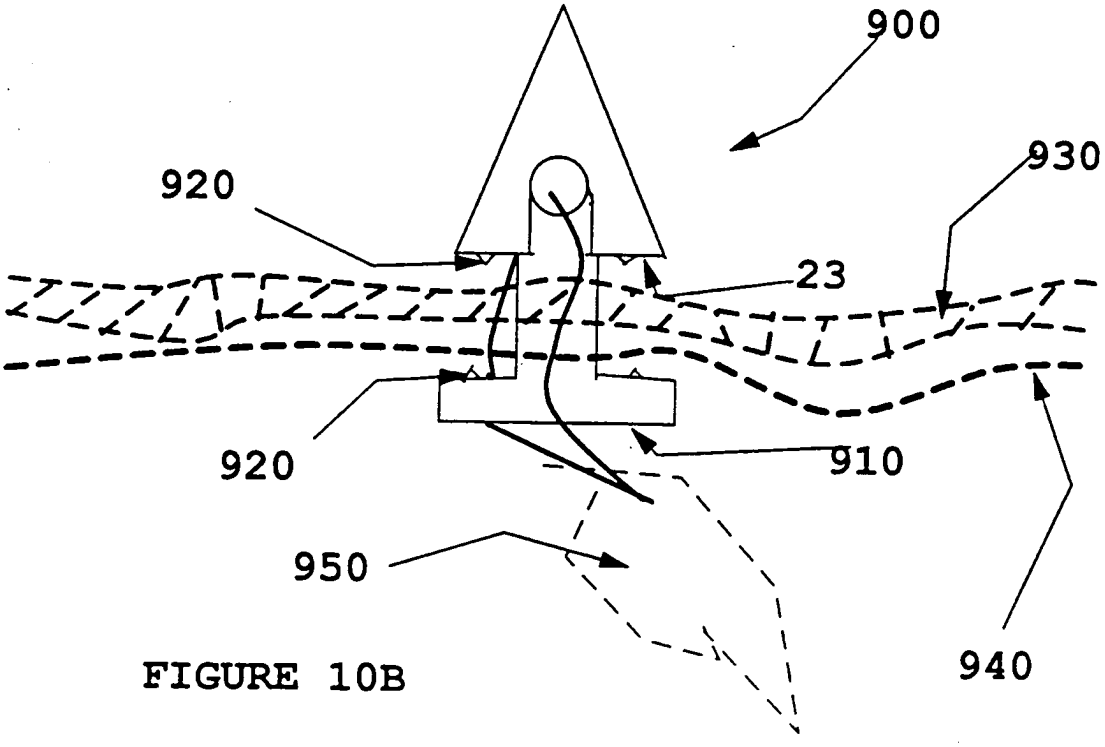

FIGURE 10B

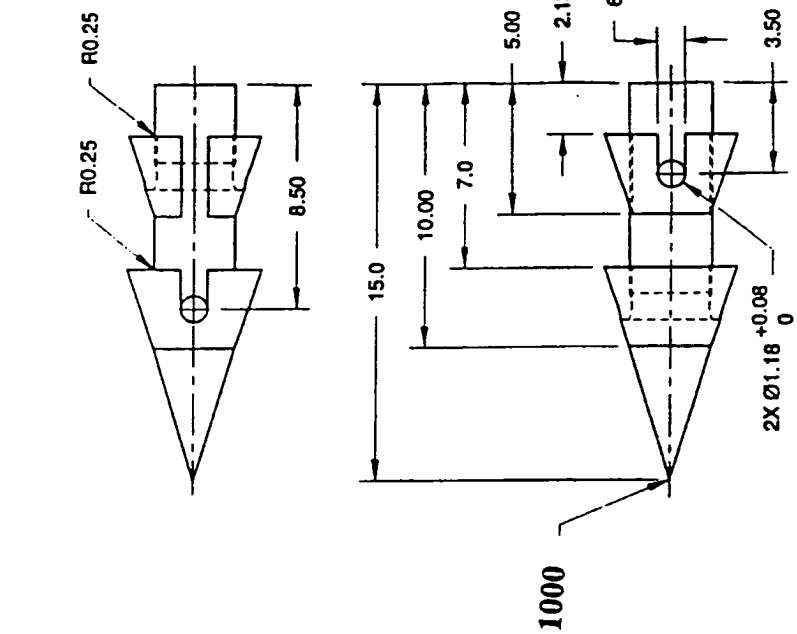

FIGURE 11C

FIGURE 11D

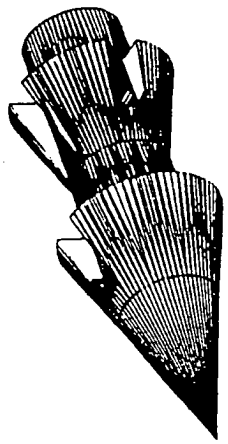

FIGURE 11A

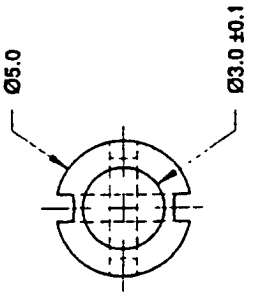

FIGURE 11B

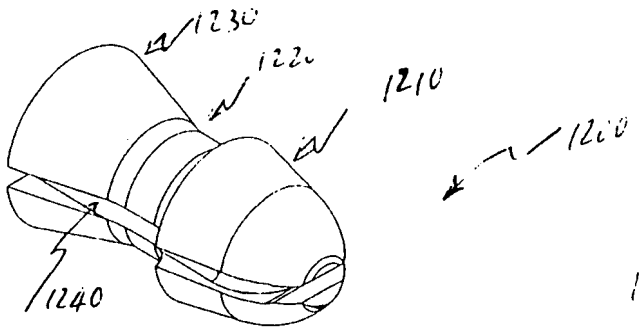

FIGURE 12A

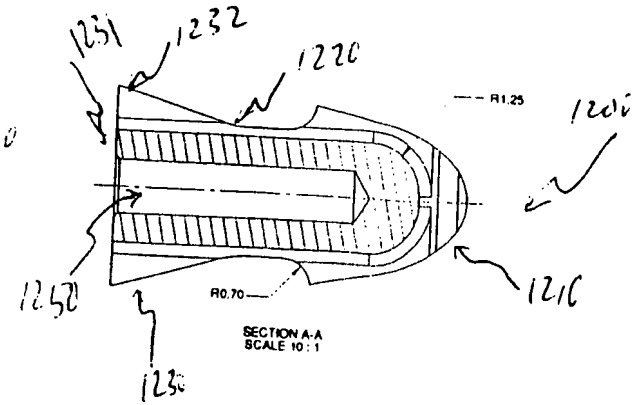

FIGURE 12B

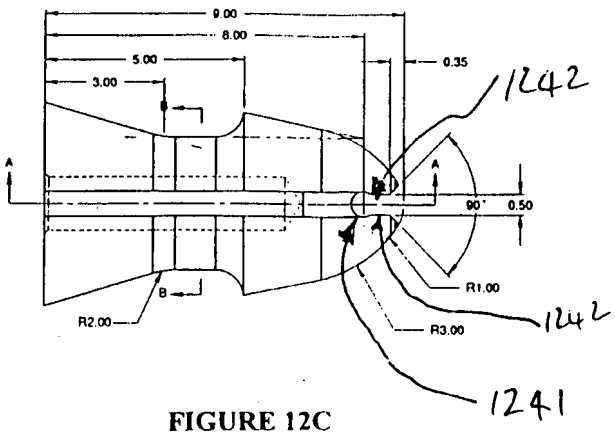

FIGURE 12C

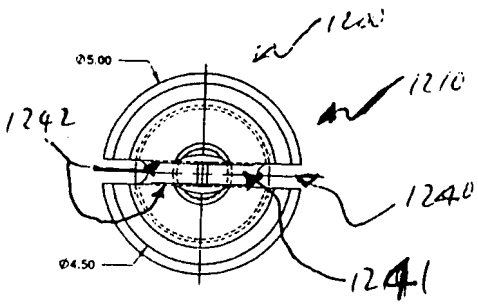

FIGURE 12D

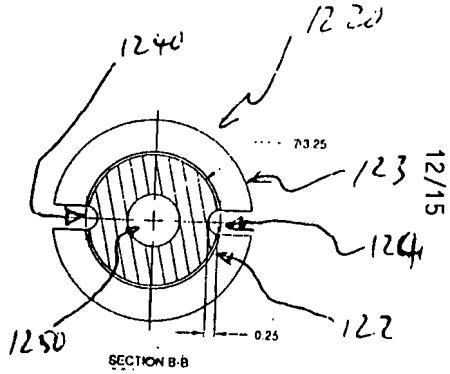

FIGURE 12E

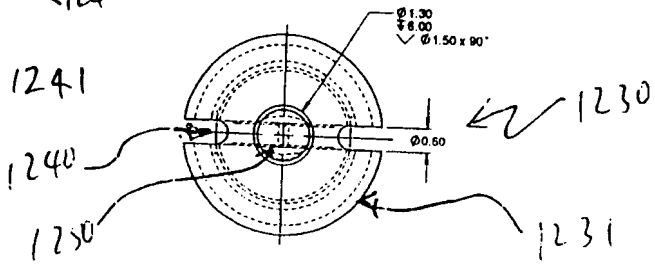

FIGURE 12F

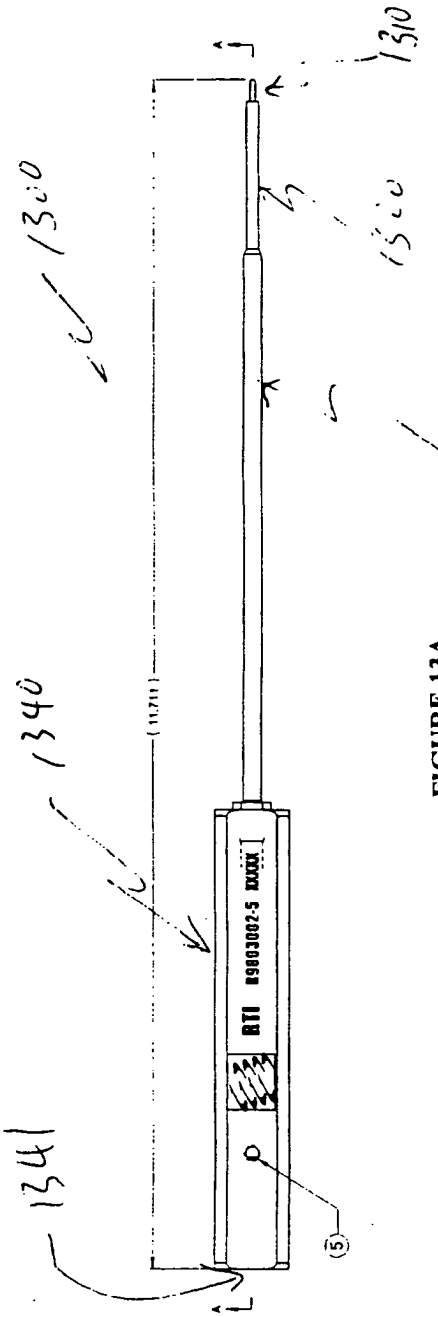

FIGURE 13A

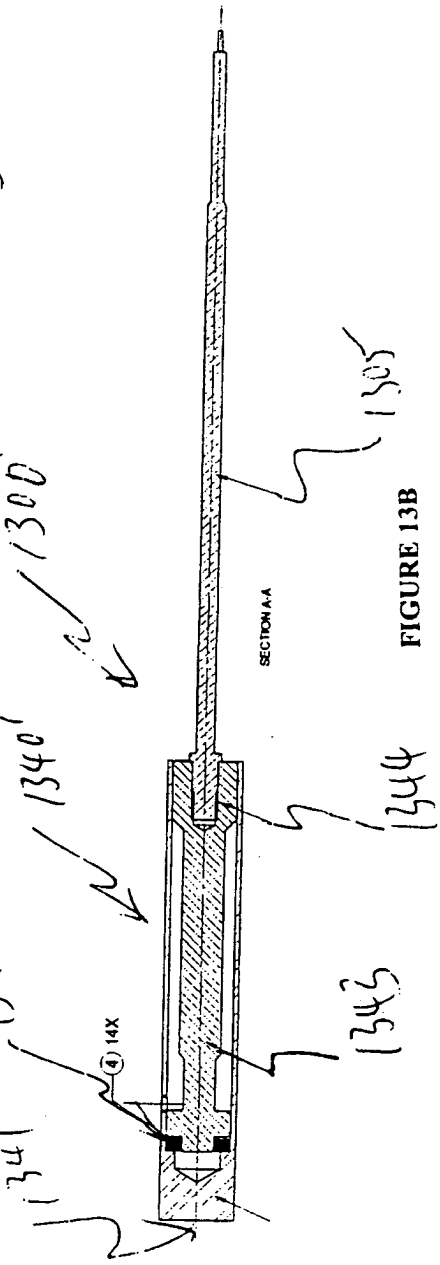

FIGURE 13B

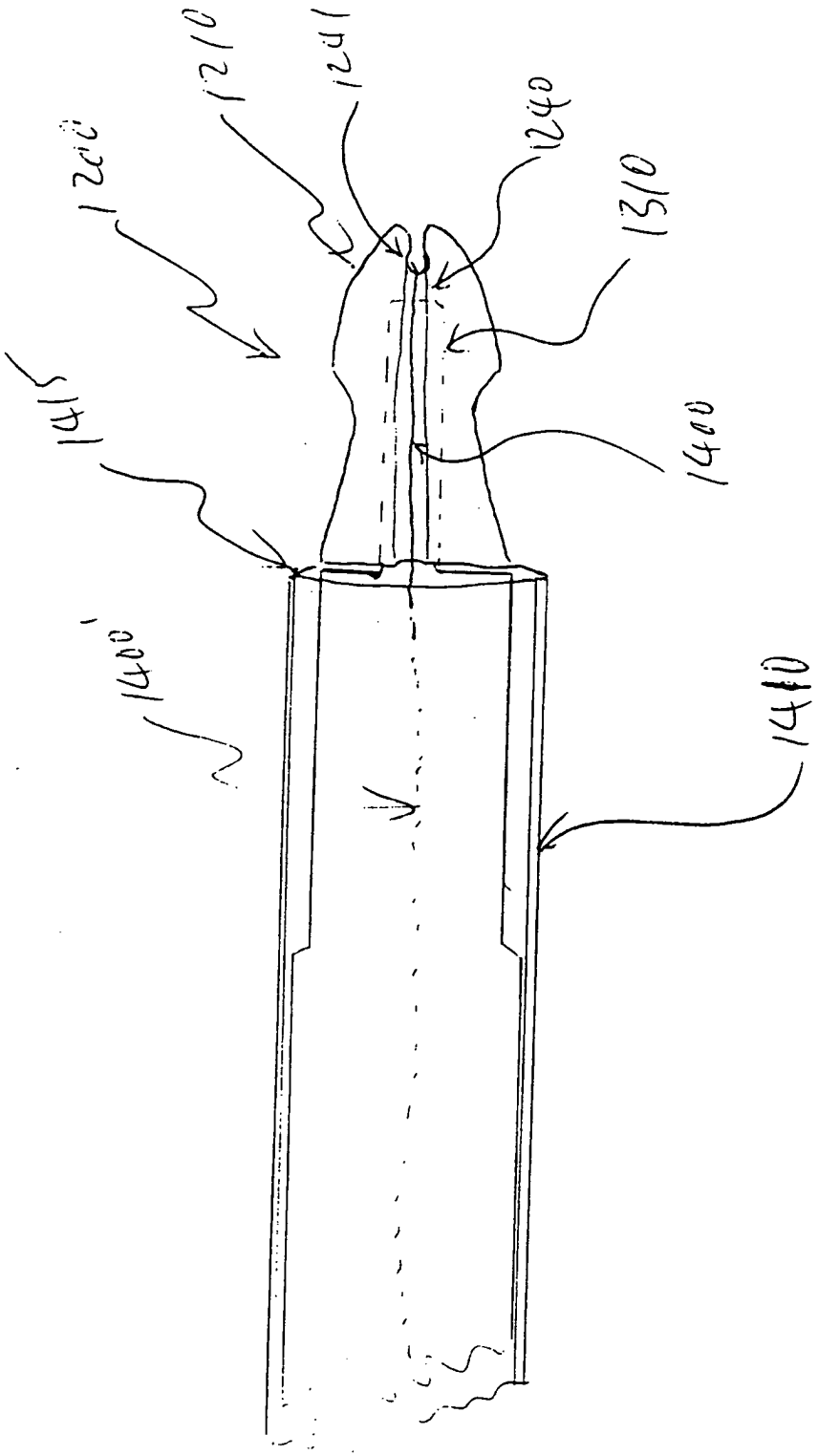

FIGURE 14

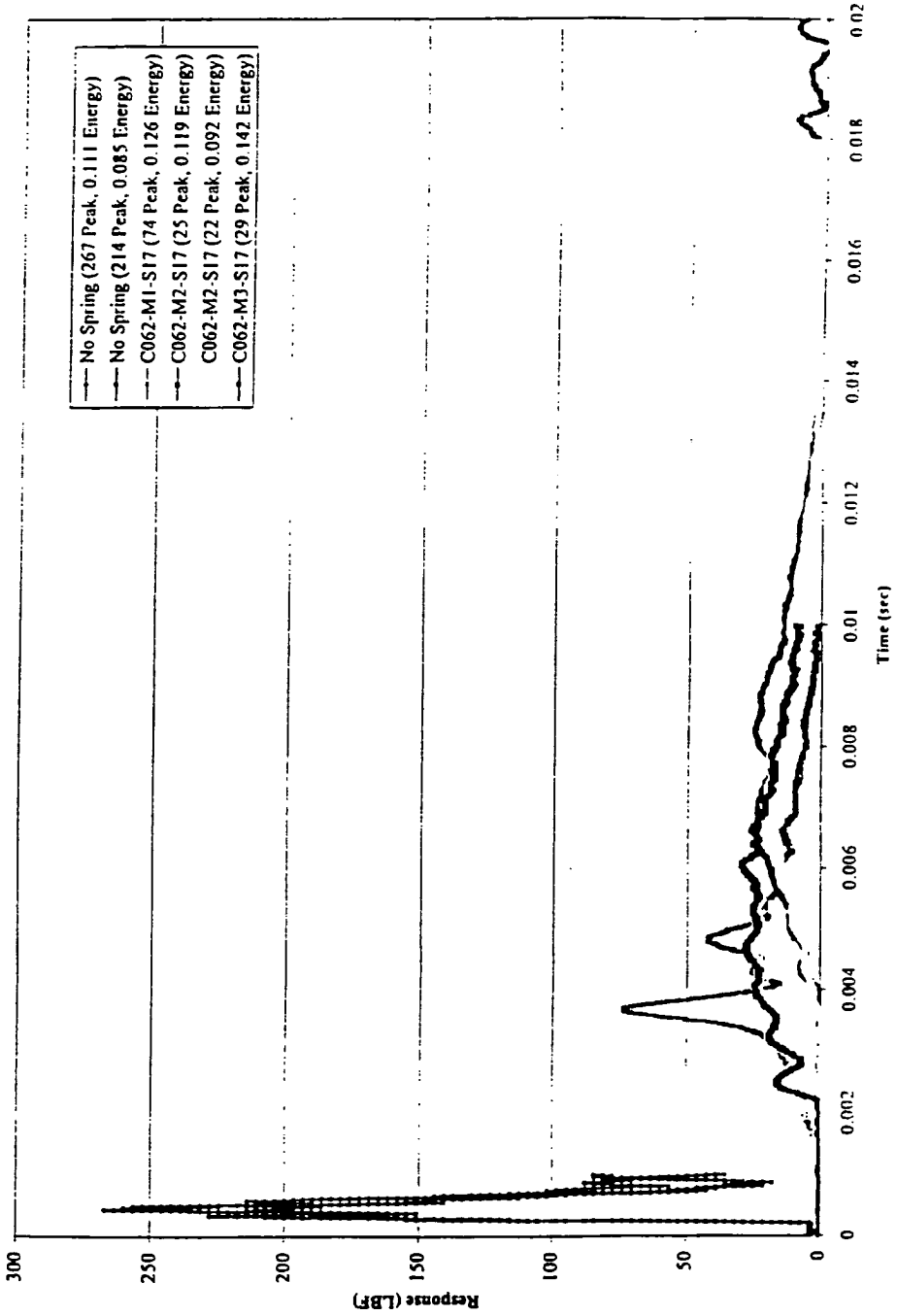
No Spring (267 Peak, 0.111 Energy)
No Spring (214 Peak, 0.085 Energy)
C062-M1-S17 (74 Peak, 0.126 Energy)
C062-M2-S17 (25 Peak, 0.119 Energy)
C062-M2-S17 (22 Peak, 0.092 Energy)
C062-M3-S17 (29 Peak, 0.142 Energy)
Response (LBF)
300
250
200
150
100
50
0
0
0.002
0.004
0.006
0.008
0.01
0.012
0.014
0.016
0.018
0.02
Time (sec)

FIGURE 15